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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,653	06/05/2000	David V. Sangar	UTSG.231US	8912

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EXAMINER

SCHEINER, LAURIE A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/27/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/587,653

Applicant(s)

Sangar et al.

Examiner

Laurie Scheiner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 30, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above, claim(s) 1-18, 22-26, and 34-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21 and 27-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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Claims 1-18, 22-26 and 34-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7. It is noted that newly added claims 51-55 are also withdrawn from consideration as being drawn to a nonelected invention since the methods therein are ultimately limited to nucleotides which differ in structure from the nucleotides of the elected method claims. Moreover, the examiner had erred in Paper No. 6 when initially assigning all polynucleotides and constructs to Group I. Thus, upon further consideration, the examiner would have imposed an additional (consistent with the above) restriction requirement had applicants elected Group I.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 19-21 and 28-30 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The methods of producing a virus, as claimed, have the same process steps and utility as that found in nature and therefore do not constitute patentable subject matter. In the absence of the hand of man, the naturally occurring viral replication is considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, mere purity of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426 (1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273 F. Supp. 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co., 283 US 1 (1931); Funk Brother Seed Co. v. Kalo Inoculant Co., 283 US 127 (1984). It is further noted that the recitation of "synthetic", in claim 30, as a term is meaningless

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with respect to distinguishing from that which occurs in nature since respective structures do not differ. Amending the claims to recite a limitation, such as, "isolated virus", is suggested to obviate this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-21 and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: isolating virus from the host cell.

The term "comprising a polynucleotide encoding a 3' sequence" in claim 19 renders the claim indefinite. The term "comprising a polynucleotide encoding a 3' sequence" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite length of the polynucleotide, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. That is, "comprising a...3' sequence" encompasses a full-length molecule, as well as a codon. Also, claims 19-21 and 27-33 are internally inconsistent since 3' refers to the polynucleotide orientation (due to sugar residue position), however, that which follows "encoding" necessarily refers to the amino acids (which do not contain sugar). Thus, It is assumed that the -COOH terminus is intended.

Claims 19-21 and 27-33 are vague and indefinite since a virus *per se* cannot be produced by a 3' portion of a viral genome. That is, an intact virus can be produced by expression of the entire viral genome only. Which 3' portion is intended? Applicants are reminded that the claims must be so definite as to allow their comparison with the available art and must also make it possible for the public to determine from the claims what they encompass

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and/or exclude. Definite claim language is important for at least two reasons. First, a member of the public must be able to understand what is encompassed by the claims for potential infringement purposes. Second, the claims must be drafted in a definite manner in order that the subject matter may be reasonably compared with the prior art. It has been indicated in several prior decisions that claims may be too indefinite to be examined with respect to the prior art. It is asserted that determining anticipation in the present case would involve the type of "speculation" proscribed by the decision in *In re Steele*. That is, in *In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962), the court pointed out that before the claimed subject matter could properly be compared to the prior art, it was essential to know what in fact the claims did cover.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-21 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Simons et al.

Simons et al. (C24). teach, at page 3401, passage of the "GB agent" in tamarins and other primate hosts. Therefore, the reference clearly and/or inherently teaches that which is claimed.

Claims 19-21 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Muerhoff et al. (C17). Muerhoff et al. teach the cloning of the GBV-B from the serum of a GBV-B infected tamarin. Thus, it is asserted that the replication of GBV-B in the tamarin reads on that which is claimed.

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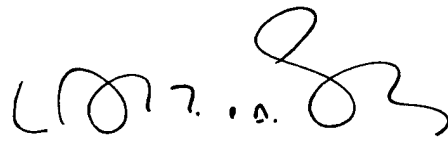
Claims 19-21 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarselli et al. Scarselli et al., Simons et al. (C24), and Muerhoff et al. (C17) are cumulative in their respective teachings of GBV-B replication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.


Laurie Scheiner/LAS
March 22, 2002


LAURIE SCHEINER
PRIMARY EXAMINER